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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,925	05/30/2001	Richard J. Feldmann	3124-Z	5146

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Law Office of Jim Zegeer  
801 North Pitt Street, #108  
Alexandria, VA 22314

EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/866,925

Applicant(s)

FELDMANN, RICHARD J.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

The Applicants have cancelled all previously pending claims and added new claims 20-37 in the amendment filed 30 October 2002. All pending claims are drawn to a computer mediated method of detection of connectrons and are roughly equivalent to originally pending Group 2. All pending claims are considered to be drawn to a single invention. The applicants actions have resulted in an election without traverse of the invention to which newly filed claims 20-37 are drawn. An action on the merits of the elected invention is detailed below.

### ***Specification***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the following reasons:

Numerous nucleotide sequences appear throughout the specification that are not properly identified. Nucleotide sequences must be identified by sequence identification number. Furthermore, if said sequences do not appear in the sequence listing, a new listing including said sequences must be supplied. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 2422.02). If said sequences consist of a portion of sequences already of record in the sequence listing, they may be identified in the specification using the existing Seq ID No. accompanied by the position of the sequence on the already listed sequence.

Applicants are required to comply with all the requirements of 37 CFR §§ 1.821-1.825. Any response to this Office Action which fails to meet all of these requirements will be

considered non-responsive. The nature of the sequences disclosed in the instant application has allowed an examination on the merits, the results of which are communicated below.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 24. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Note that deletion of the term “http://:” will serve to disable the embedded hyperlink.

The disclosure is objected to because of the following informalities:

Figure 11 page 3 is not described in the brief description of the drawings on page 25 of the specification.

The index on pages 37 and 38 should be amended to delete page numbers because any patent that might issue from the instant application will have column numbers and not page numbers.

On page 28, line 15, the reference listed with the bibliography number “[1]” does not correspond to the reference listed in the bibliography.

Appropriate correction is required.

A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because correction of the deficiencies detailed above would require excessive effort by the Office to enter as an amendment due to the length of the required amendment.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement

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that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

### ***Claim Objections***

Claims 20 and 36 are objected to because of the following informalities: In claim 20, line 4, the term "of" should be deleted. In claim 36, line 2, the term "do" should be amended to recite "does." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must identify and use a connectron to predict regulation of gene expression. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The description provides guidance to identify connectron symmetries in genomic sequences. The description does not provide detailed guidance to use identified connectron symmetries to predict an effect on gene expression.

c) The description provides working examples of identification of connectron symmetries in genomic sequences. The description does not provide working examples of using identified connectron symmetries to predict effects on gene expression.

d) The nature of the invention, gene expression control, is complex.

e) The prior art does not show connectrons. Mattick (published in 2001, one year after the effective instant filing date) reviews effects of RNA molecules on gene regulation. Mattick does not show connectrons as defined in the instant specification.

f) The skill of those in the art of gene expression is high.

g) The predictability of the relationship of connectron symmetries and gene expression is unknown in the prior art.

h) The claims are broad in that they are drawn to identification of connectron symmetries whose relationship to gene expression is not established.

The skilled practitioner would first turn to the instant description for guidance in using the claimed invention. However, the description lacks clear evidence that connectron symmetries are related to gene expression. As such, the skilled practitioner would turn to the prior art for

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such guidance, however the prior art does not discuss connectron symmetries. Finally, said practitioner would turn to trial and error experimentation to determine a relationship between connectron symmetries and gene expression. Such amounts to undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 22-25, and 28-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite because it is not clear whether the claim is drawn to a method of modifying nucleic acid molecules or a method of computer mediated identification of connectron organization. The rejection would be overcome by amending claim 25 to delete the preamble reference to modification of a genome.

Claims 20 and 28-37 are indefinite because of the recitation in claim 20 of the phrase one RNA molecule comprising of two RNA sequences” because it is not clear how the limitation of comprising two RNA sequences further limits the RNA molecule. The rejection would be overcome by amending claim 20 to further limit a first RNA sequence that can hybridize to a first non-adjacent DNA sequence and a second RNA sequence that can hybridize to a second non-adjacent DNA sequence.

Claims 20 and 28-37 are indefinite because of the recitation of the phrase “detecting, by computer, one or more pairs of non-adjacent DNA sequences to which are bound one RNA molecule” because it is not clear how a DNA sequence database can bind RNA molecules. The

rejection would be overcome by amending claim 20 to recite “detecting, by computer, one or more pairs of first and second non-adjacent DNA sequences which could hybridize to one RNA molecule.”

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: a step of modifying expression of different gene collections in a genome. The rejection would be overcome by amending claim 22 to be drawn to a computer mediated method of detecting changes in expression of different gene collections in a genome.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: a step of detecting where and when genes are integrated. The rejection would be overcome by amending claim 23 to be drawn to a computer mediated method of detecting links between newly introduced genes and preexisting connectrons.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: a step of detection of the effect of gene collections on expression because it is not clear that the recited step of detecting transacting behavior is equivalent to detection of expression effects. The rejection would be overcome by amending claim 24 to be drawn to a computer mediated method of detecting the effect of connectrons on transcription.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: a step of modification of nucleic acid molecules. The rejection



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would be overcome by amending claim 25 to be drawn to a method of computer mediated identification of connectron organization.

Claim 23 recites the limitations "the operable link", "the newly introduced gene", and "the existing connectron behavior." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 23 to recite "an operable link", "a newly introduced gene", and "a preexisting connectron behavior"

Claim 28 recites the limitation "the tetradic relationship." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 28 to recite "where the DNA sequence and the RNA molecule can form a tetradic relationship such that."

Claims 29 and 30 recite the limitation "the connectron relationship." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claims 29 and 30 to recite "where the DNA sequence and the RNA molecule function as a connectron."

Claim 31 recites the limitation "the connectron relationships between prokaryotes and their plasmids." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 31 to recite "where the DNA sequence and the RNA molecule function as a connectron between prokaryotes and their plasmids."

Claim 32 recites the limitation "the connectron relationships that exist in plant or higher animals." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 32 to recite "where the DNA sequence and the RNA molecule function as a connectron that exists in a plant or a higher animal."

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Claim 33 recites the limitation "the connectron relationship." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 33 to recite "where the DNA sequence and the RNA molecule function as a connectron."

Claim 34 recites the limitation "the connectron relationship." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 34 to recite "where the DNA sequence and the RNA molecule function as a connectron."

Claim 35 recites the limitation "the connectron relationship." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 35 to recite "where the DNA sequence and the RNA molecule function as a connectron."

Claim 36 recites the limitation "the connectron relationship." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 36 to recite "where the DNA sequence and the RNA molecule function as a connectron."

Claim 37 recites the limitation "the geneless connectron relationship." There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 37 to recite "where the DNA sequence and the RNA molecule function as a geneless connectron."

For the purpose of examination, the claims have been assumed to incorporate the suggested amendments.

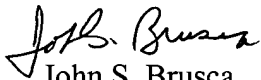
### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb  
January 6, 2003